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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,812	09/01/2000	Haig H. Kazazian JR.	53893-5006-02	6101

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/653,812	Applicant(s) KAZAZIAN ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 05 December 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

No amendments were presented.

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 34,36-44,46,47 and 49.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

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Continuation Sheet (PTOL-303)

Continuation of 5. Applicants' reply has overcome the following:

The objection to the Declaration filed March 23, 2005 is withdrawn in view of the newly filed Declaration of December 5, 2005.

Continuation of 7. For purposes of appeal, the proposed amendment(s): ...

To clarify for the record, although the after final response filed December 5, 2005 is titled "Amendment" and presents a replacement claims listing, no amendments have been presented.

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

New Evidence Presented After Final Rejection. With regard to the new evidence presented after final rejection (Besse et al., 2003; Ostertag et al. 2002; and Prak et al., 2003), it is noted that new evidence traversing rejections is not considered timely when filed after a final rejection, unless submitted in response to a new ground of rejection made in the final rejection. In this case, no new ground of rejection was made in the final rejection. See MPEP 716.01. Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted prior to a final rejection or after final rejection and submitted with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection. See MPEP 716.01.

At page 5, paragraph 5 of the response, Applicants refer to their arguments presented in their responses of April 16, 2002 and March 21, 2005 and incorporate them by reference in their entirety. These arguments have already been fully addressed in the Office Actions of September 22, 2004 and June 2, 2005 and will not be reiterated here.

Continuation Sheet (PTOL-303)

At page 6, paragraph 1 of the response, Applicants assert that the use of the claimed transgenic mouse and sperm cell reasonably correlates with the entire scope of the claim and therefore precludes an enablement rejection. At page 6, paragraph 2 of the response, Applicants point to the specification at page 28, lines 14-16, and assert that the specification as filed “provides the skilled artisan with enablement for using the transgenic mouse in elucidating animal and human gene function and evaluating targets for gene therapy.” Applicants go on to point specifically to using an L1-expressing transgenic animal to study the biology of mammalian retrotransposition. Applicants further assert that the transgenic mouse is extremely useful in understanding the process of retrotransposition and its effect on the mammalian genome. First, it is noted that the cited section of the specification does not mention using the transgenic mouse in elucidating animal and human gene function and evaluating targets for gene therapy, as Applicants contend. Thus, it cannot provide enablement for such uses, contrary to Applicants’ assertion. Applicants are invited to view the Office’s official copy of the application using Public PAIR. Second, for reasons detailed in the prior Office Actions, using the transgenic mouse to study the biology of mammalian retrotransposition does not rise to the level of a specific and substantial utility within the meaning of 35 U.S.C. 101, because such a use constitutes studying the claimed product, i.e. the transgenic mouse, which does not provide a real world context of use. See the Office Action of June 2, 2005 at page 7.

The remainder of the arguments rely on new evidence presented after final rejection, which has not been considered for the reasons indicated hereinabove. Therefore, these arguments are moot at the present time.

Thus, the rejection under 35 U.S.C. 112, first paragraph is maintained, for reasons of record.

Notice of Non-Compliant Amendment (37 CFR 1.121)

Application No.

09/653,812

Examiner

Anne-Marie Falk, Ph.D.

Applicant(s)

KAZAZIAN ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 05 December 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: See Claim 40.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.

PRIMARY EXAMINER